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10/500,841	02/15/2005	Naoyuki Taniguchi	034100-003	7031

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EXAMINER

CHOWDHURY, IQBAL HOSSAIN

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 06/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/500,841	Applicant(s) TANIGUCHI ET AL.	
	Examiner Iqbal Chowdhury, Ph.D.	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 8-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/04, 3/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application is a 371 of PCT/JP02/13879 filed on 12/27/2002.

The preliminary amendment filed on 3/16/2006 is acknowledged. Claim 23 has been added. Claims 1-23 are pending and are present for examination.

Applicant's election with traverse of Group I, Claims 1-7, drawn to an isolated polypeptide β 1,6-N-acetylglucosaminyltransferase and neovascularization accelerator comprising the polypeptide in the response filed on 3/16/2006 is acknowledged.

Applicant's election without traverse of Group I Claims 1-7, drawn to an isolated polypeptide β 1,6-N-acetylglucosaminyltransferase and neovascularization accelerator comprising the polypeptide in the response filed on 3/16/2006 is acknowledged. New Claim 23 is drawn to a method of accelerating neovascularization by administering an effective amount of the peptide or protein. Newly submitted claim 23 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claim 23 is a method of use of the polypeptide of Group I. As discussed in the previous office action regarding the lack of unity presence, "a DNA encoding a polypeptide β 1,6-N-acetylglucosaminyltransferase is known in the art (EP585109 A2; Suntory, Ltd., see IDS), therefore claim 23 lacks unity of invention with Group I. Accordingly, claim 23 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Accordingly, Claims 8-22 are also withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

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Claims 1-7 are at issue and are present for examination.

Priority

Acknowledgement is made of applicants claim for foreign priority application JAPAN 2002-2056 of 1/9/2002.

Claim Objections

Claim 4 is objected to as the recitation “30% or more” is grammatically incorrect “greater than 30%” is suggested. Appropriate corrections are required.

Claim 7 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 7 is not further limiting of claim 6 as it merely recites intended use of the claimed product. As recitation of an intended use adds no limitation to the product and the claim does not further limit claim 6.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-5 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

In the absence of the hand of man, naturally occurring nucleic acids and /or proteins are considered non-statutory subject matter. *Diamond and Chakrabarty*, 206 USPQ 193 (1980). This rejection may be overcome by amending the claims to contain wording such as “An isolated peptide or protein”. For examination purpose the claim is read as such.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite and vague for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 3 is indefinite and vague in the recitation of the “amino acid sequence as depicted in SEQ ID NO: 6, which is ambiguous and confusing. SEQ ID NO: 6 is a nucleic acid sequence not an amino acid sequence. Clarification is required.

Claims 6 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite and vague for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 6 is indefinite and vague in the recitation of the “a neovascularization accelerator”, which is ambiguous and confusing. Does it include the presence of anything beyond the claim 1 having neovascularization activity? Claim 7 is rejected as it depends on claim 6. Clarification is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-7 are directed to a genus of a peptide or a protein having a neovascularization accelerating activity and containing a basic amino acid cluster region of a β 1,6-N-acetylglucosaminyltransferase or any modified peptide or a protein by modification of one or more amino acids in the amino acid sequence encoded by SEQ ID NO: 6 or modification of one or more amino acids in the amino acid sequence of SEQ ID NO: 7. As discussed in the written description guidelines the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. A representative number of species means that the species, which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. The specification teaches the structure of only a single representative species of such proteins. Claims 2 adds some additional characteristics of the β 1,6-N-acetylglucosaminyltransferase from which the basic amino acid cluster region is derived but fails to define the structural characteristics of the remainder of the protein having neovascularization activity and there is no evidence to suggest that the basic amino acid cluster region of SEQ ID NO: 7 has neovascularization activity alone. Similarly, while claim 4 also add an additional characteristic to the limitations of the genus of claim 1 i.e. the number of basic amino acids within the basic amino acid cluster region accounts for 30% or more of the total number of

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amino acids in said region (claim 4), this characteristic alone is not sufficient to change the fact that the claims include proteins which are highly variable in structure as this characteristic defines the structural characteristics of only a very small region of the protein having neovascularization activity without defining the structure of the remainder at all and furthermore does not even fully define the structure of the basic cluster region. Thus for all the reasons discussed, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a protein having neovascularization accelerating activity encoded by SEQ ID NO: 6 from human with identifying properties such as converting of N-acetylglucosamine into α -6-D-mannoside using UDP-N-acetylglucosamine as substrate, specificity as defined in claim 2, optimum pH (6.2 to 6.3), non-requirement of Mn^{2+} for activity, resistant to EDTA even at 20 mM concentration, molecular weight 73,000 in absence of reducing agent and 60,000-70,000 in presence of reducing agent, K_m values such as 133 μM for GnGn-bi-PA and 3.5 mM for UDP-GlcNAc and having five peptide fragments (claim 2) and a basic amino acid cluster region in which the number of basic amino acids accounts for 30% or more of the total number of amino acids in said region (claim 4) and basic amino acid sequence of SEQ ID NO: 7 (claim 5), does not reasonably provide enablement for any peptide or any protein having neovascularization activity from any source or any protein sequence with modification of one or more amino acids or any peptide sequence with modification of one or more amino acids to

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SEQ ID NO: 7. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Claims 1-7 are so broad as to encompass any peptide or any protein having neovascularization activity and comprising a basic amino acid cluster from any β 1,6-N-acetylglucosaminyltransferase from any source or any protein sequence with modification of one or more amino acids or any peptide sequence with modification of one or more amino acids to SEQ ID NO: 7. Claims 2-5 recite any peptide having neovascularization activity and comprising the basic amino acid cluster region of a well defined β 1,6-N-acetylglucosaminyltransferase (claim 2) or wherein the number of basic amino acids in the basic amino acid cluster region accounts for 30% or more of the total number of amino acids in said region (claim 4) or wherein the protein comprises basic amino acid sequence of SEQ ID NO: 7 or a variant thereof (claim 5). The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of proteins or peptides broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the nucleotide and encoded amino acid sequence of only one protein having neovascularization activity (i.e. that encoded by SEQ ID NO: 6).

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple point mutations or substitutions.

The specification does not support the broad scope of the claims which encompass any peptide or any protein having neovascularization activity or any protein sequence with modification of one or more amino acids or any peptide sequence with modification of one or more amino acids because the specification does not establish: (A) regions of the protein structure which may be modified without effecting neovascularization activity; (B) the general tolerance of protein to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any protein residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any peptide or any protein having neovascularization activity or any protein sequence with modification of one or more amino acids to protein encoded by SEQ ID NO: 6 or any peptide sequence with modifications of one or more amino acids to SEQ ID NO: 7. The scope of the claims must bear a reasonable correlation with the scope of enablement

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(In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of any peptide or protein having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Taniguchi et al. (US Patent 5,834,284, publication 11/10/1998, see IDS). Taniguchi et al. disclose a beta1,6-N-acetylglucosaminyl transferase protein (SEQ ID NO: 8), which is 100% identical to a protein encoded by SEQ ID NO: 6 and comprises a region 100% identical to SEQ ID NO: 7 (amino acid 254 - amino acid 269) of the instant application. Taniguchi et al. also disclose that the protein having the following properties: (1) Action: it transfers N-acetylglucosamine from UDP-N-acetylglucosamine to alpha-6-D-mannoside; (2) Substrate specificity: it shows a reactivity of about 79% for GnGnF-bi-PA, about 125% for GnGnGn-tri-PA and about 66% for GnM-Pa, when taking a reactivity for GnGn-bi-PA as 100%; (3) Optimum pH: 6.2 to 6.3; (4) Inhibition, Activation and Stability: Mn^{2+} is not necessary for expression of activity, and the activity is not inhibited in the presence of 20 mM EDTA; (5) Molecular weight: about 73,000 as determined by SDS-PAGE in the absence of reducing agent; and about 73,000 and about 60,000 as determined

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in the presence of a reducing agent; (6) Km value: 133 uM and 3.5 mM for acceptor GnGn-bi-PA and donor UDP-GlcNAc, respectively; and (7) It includes the following peptide fragments: (SEQ ID NO: 1) Thr-Pro-Trp-Gly-Lys, (SEQ ID NO: 2) Asn-Ile-Pro-Ser-Tyr-Val, (SEQ ID NO: 3) Val-Leu-Asp-Ser-Phe-Gly-Thr-Glu-Pro-Glu-Phe-Asn-His-Ala-Asn-Tyr-Ala, (SEQ ID NO: 4) Asp-Leu-Gln-Phe-Leu-Leu and (SEQ ID NO: 5) Asn-Thr-Asp-Phe-Phe-Ile-Gly, and gene coding for said enzyme, and a process for production of the enzyme. Thus Taniguchi et al. inherently disclose a protein having the function of neovascularization accelerating activity or wound healing activity or activity for preventing arteriosclerosis. Therefore, Taniguchi et al. anticipates claims 1-7 of the instant application.

Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Taniguchi et al. (EP 0585109 A2, publication 3/2/1994, see IDS). Taniguchi et al. disclose a beta1,6-N-acetylglucosaminyl transferase protein (SEQ ID NO: 8), which is 100% identical to a protein encoded by SEQ ID NO: 6 and comprises a region 100% identical to SEQ ID NO: 7 (amino acid 254 - amino acid 269) of the instant application. Taniguchi et al. also disclose that the protein having the following properties: (1) Action: it transfers N-acetylglucosamine from UDP-N-acetylglucosamine to alpha-6-D-mannoside; (2) Substrate specificity: it shows a reactivity of about 79% for GnGnF-bi-PA, about 125% for GnGnGn-tri-PA and about 66% for GnM-Pa, when taking a reactivity for GnGn-bi-PA as 100%; (3) Optimum pH: 6.2 to 6.3; (4) Inhibition, Activation and Stability: Mn^{2+} is not necessary for expression of activity, and the activity is not inhibited in the presence of 20 mM EDTA; (5) Molecular weight: about 73,000 as determined by SDS-PAGE in the absence of reducing agent; and about 73,000 and about 60,000 as determined in the presence of a reducing agent; (6) Km value: 133 uM and 3.5 mM for acceptor GnGn-bi-

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PA and donor UDP-GlcNAc, respectively; and (7) It includes the following peptide fragments: (SEQ ID NO: 1) Thr-Pro-Trp-Gly-Lys, (SEQ ID NO: 2) Asn-Ile-Pro-Ser-Tyr-Val, (SEQ ID NO: 3) Val-Leu-Asp-Ser-Phe-Gly-Thr-Glu-Pro-Glu-Phe-Asn-His-Ala-Asn-Tyr-Ala, (SEQ ID NO: 4) Asp-Leu-Gln-Phe-Leu-Leu and (SEQ ID NO: 5) Asn-Thr-Asp-Phe-Phe-Ile-Gly, and gene coding for said enzyme, an expression vector, host cell and a process for production of the enzyme. Thus, the protein recited by Taniguchi et al. inherently is a protein having the function of neovascularization accelerating activity or wound healing activity or activity for preventing arteriosclerosis. Therefore, Taniguchi et al. anticipates claims 1-7 of the instant application.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,707,846. An obviousness-type

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double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

Claims 1-7 of the instant application is directed to a peptide or protein having a neovascularization action and containing a basic amino acid cluster region of beta-1,6-N-acetylglucosaminyltransferase (claim 1) and a peptide or a protein, wherein the β 1,6-N-acetylglucosaminyltransferase has the following properties: (1) Action: it transfers N-acetylglucosamine from UDP-N-acetylglucosamine to alpha-6-D-mannoside; (2) Substrate specificity: it shows a reactivity of about 79% for GnGnF-bi-PA, about 125% for GnGnGn-tri-PA and about 66% for GnM-Pa, when taking a reactivity for GnGn-bi-PA as 100%; (3) Optimum pH: 6.2 to 6.3; (4) Inhibition, Activation and Stability: Mn^{2+} is not necessary for expression of activity, and the activity is not inhibited in the presence of 20 mM EDTA; (5) Molecular weight: about 73,000 as determined by SDS-PAGE in the absence of reducing agent; and about 73,000 and about 60,000 as determined in the presence of a reducing agent; (6) Km value: 133 μ M and 3.5 mM for acceptor GnGn-bi-PA and donor UDP-GlcNAc, respectively; and (7) It includes the following peptide fragments: (a) Thr-Pro-Trp-Gly-Lys, (b) Asn-Ile-Pro-Ser-Tyr-Val, (c) Val-Leu-Asp-Ser-Phe-Gly-Thr-Glu-Pro-Glu-Phe-Asn-His-Ala-Asn-Tyr-Ala, (d) Asp-Leu-Gln-Phe-Leu-Leu and (e) Asn-Thr-Asp-Phe-Phe-Ile-Gly (claim 2). Claim 3 recites that

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the peptide or protein according to claim 1, wherein the beta-1,6-N-acetylglucosaminyltransferase has an amino acid sequence encoded by the SEQ ID NO: 6, or an amino acid sequence obtained by modification of one or more amino acids in this amino acid sequence and Claim 4 recites that the peptide or protein according to claim 1, wherein, in the basic amino acid cluster region, the number of basic amino acids accounts for 30% or more of the total number of amino acids in said region. Claim 5 recites that the peptide or protein according to claim 1, wherein the basic amino acid cluster region contains at least an amino acid sequence as depicted in SEQ ID NO: 7 or an amino acid sequence obtained by modification of one or more amino acids in this amino acid sequence and claim 6 recites that a neovascularization accelerator containing the peptide or protein according to claim 1. Claim 7 recites that the neovascularization accelerator according to claim 6, wherein it is a wound healing agent or a preventing and/or therapeutic agent for arteriosclerosis.

Claim 1 of U.S. Patent No. 5,707,846 is directed to a protein having beta1,6-N-acetylglucosaminyl transferase activity (SEQ ID NO: 8), which is 100% identical to a protein encoded by SEQ ID NO: 6 and comprises a region 100% identical to SEQ ID NO: 7 (amino acid 254 - amino acid 269) of the instant application and having the following properties: (1) Action: it transfers N-acetylglucosamine from UDP-N-acetylglucosamine to alpha-6-D-mannoside; (2) Substrate specificity: it shows a reactivity of about 79% for GnGnF-bi-PA, about 125% for GnGnGn-tri-PA and about 66% for GnM-Pa, when taking a reactivity for GnGn-bi-PA as 100%; (3) Optimum pH: 6.2 to 6.3; (4) Inhibition, Activation and Stability: Mn^{2+} is not necessary for expression of activity, and the activity is not inhibited in the presence of 20 mM EDTA; (5) Molecular weight: about 73,000 as determined by SDS-PAGE in the absence of reducing agent;

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and about 73,000 and about 60,000 as determined in the presence of a reducing agent; (6) Km value: 133 uM and 3.5 mM for acceptor GnGn-bi-PA and donor UDP-GlcNAc, respectively; and (7) It includes the following peptide fragments: (SEQ ID NO: 1) Thr-Pro-Trp-Gly-Lys, (SEQ ID NO: 2) Asn-Ile-Pro-Ser-Tyr-Val, (SEQ ID NO: 3) Val-Leu-Asp-Ser-Phe-Gly-Thr-Glu-Pro-Glu-Phe-Asn-His-Ala-Asn-Tyr-Ala, (SEQ ID NO: 4) Asp-Leu-Gln-Phe-Leu-Leu and (SEQ ID NO: 5) Asn-Thr-Asp-Phe-Phe-Ile-Gly, and gene coding for said enzyme, and a process for production of the enzyme. Claim 1 of U.S. Patent No. 5,707,846 anticipates claims 1-7 of the instant application as written as the protein recited by U.S. Patent No. 5,707,846, inherently is a protein having the function of neovascularization accelerating activity or wound healing activity or activity for preventing arteriosclerosis. Therefore, U.S. Patent No. 5,707,846 anticipates claims 1-7 of the instant application.

Conclusion

Status of the claims:

Claims 1-7 are pending.

Claims 1-7 are rejected.

No claim is in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iqbal Chowdhury whose telephone number is 571-272-8137. The examiner can normally be reached on 9:00-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

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